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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,056	05/22/2006	Peter Joseph Ayre	115427.00004	3676

72535 7590 07/21/2008

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EXAMINER	
SAIDI, AZADEH	
ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
07/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,056	AYRE ET AL.	
	Examiner	Art Unit	
	Anita Saidi	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to Applicant's arguments filed on 03 March 2008. Examiner acknowledges the amendments to claims 1 and 3-9, the cancellation of claim 2 and the addition of new claims 10-26. Currently claims 1 and 3-26 are pending.

Response to Arguments

2. Applicant's arguments, see page 8, filed on 03 March 2008, with respect to defectiveness of the declaration have been fully considered and are persuasive. The objection to the declaration has been withdrawn.

3. Applicant's arguments, see page 9, filed on 03 March 2008, with respect to the rejection of claims 1-9 under 35 USC 112 first paragraph have been fully considered and are persuasive. Said rejection of claims 1-9 has been withdrawn.

4. Applicant's arguments, see page 10, filed on 03 March 2008, with respect to the rejection of claims 5, 8 and 9 under 35 USC 112 second paragraph have been fully considered and are persuasive. Said rejection of claims 5, 8 and 9 has been withdrawn.

5. Applicant's arguments, see page 10, filed on 03 March 2008, with respect to the rejection of claims 1-9 under 35 USC 101 have been fully considered and are persuasive. Said rejection of claims 1-9 has been withdrawn.

6. Applicant's arguments, see pages 10-12, filed on 03 March 2008, with respect to the rejection(s) of claim(s) 1, 2 and 6 under 35 USC 102 (b) as being anticipated by Barker have been fully considered and are persuasive. Therefore, the rejection has

been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the newly amended claims and the newly found art.

7. Applicant's arguments, see pages 12-13, filed on 03 March 2008, with respect to the rejection(s) of claim(s) 3-4 under 35 USC 103 (a) as being unpatentable by Barker in view of Cimochowski have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the newly amended claims.

8. Applicant's arguments, see pages 13-14, filed on 03 March 2008, with respect to the rejection(s) of claim(s) 5 and 7-9 under 35 USC 103 (a) as being anticipated by Barker have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the newly amended claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 3-5, 8-10, 12-17, 19-20 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,623,420 to Reich et al (Hereinafter "Reich") in view of US 6,367,333 to Bullister et al (Hereinafter "Bullister").

In reference to claims 1 and 12-13:

Reich teaches:

> An implantable blood pump (20 of Reich) which comprises an implantable cannula adapted to connect the heart of a patient to a blood pump (Col. 2, lines 24-29 and lines 54-65 of Reich). The pump includes means in the form of an inlet pressure sensor (22 of Reich) for measuring inlet pressure of the blood flow between the left ventricle and the inlet side of the pump (Col. 2, lines 42-45 of Reich). The pump also includes means in the form of an outlet pressure sensor (26 of Reich) joined to the outlet side of the pump in flow communication with the aorta by an outlet tube or catheter (28 of Reich). Reich also discloses that the pressure sensor may have any suitable form (Col. 2, lines 42-50 of Reich).

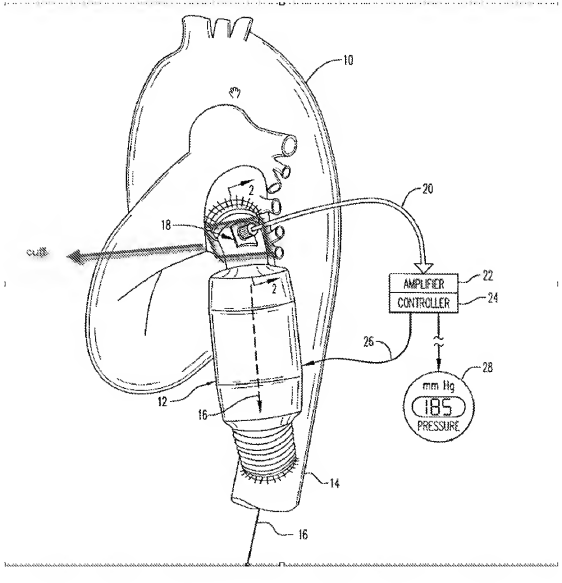
However Reich fails to disclose:

> A thin walled tubular member or a cuff with at least one pressure sensor within the cannula. The pressure sensor is positioned and adapted to non-invasively detect the pressure of blood flowing through the cannula from the heart to the pump.

Bullister, which has a common assignee as Reich, teaches:

> A tubular pressure sensor unit (18 of Bullister) joins a heart pump (12 of Bullister) in flow communication with the left ventricle for

carrying blood through the pump while simultaneously measuring pressure thereof (Col. 2, lines 44-53 of Bullister). The cannula further comprises a cuff within (the tubular section comprising element 18 of Bullister).



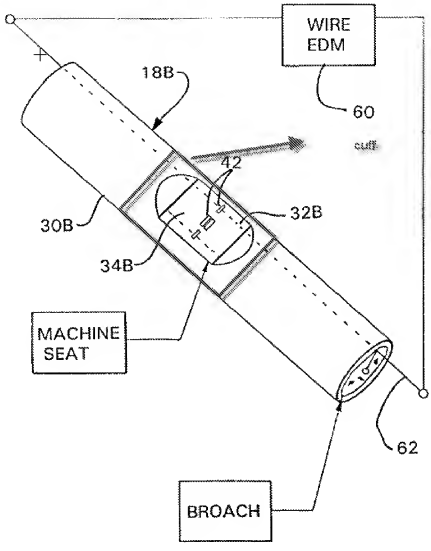


FIG. 10

The pressure sensor includes a cannula tube (30 of Bullister) through which the fluid is channeled. The tube is preferably formed from hemo-compatible material and is smooth and seamless. The tube comprises an annular thin wall with a nominal thickness (Col.

3, lines 1-6 of Bullister). A plurality of strain gauges (42 of Bullister) are mounted on top of the tube in order to measure the fluid pressure non-invasively (Fig. 2 of Bullister).

Reich fails to disclose a specific structure for the cannulas connecting the pump pressure and the blood pressure sensors attached within each cannula. Reich also incorporates Bullister in order to describe the structural limitations of the pump which includes means in the form of an inlet pressure sensor (22 of Reich) for measuring inlet pressure of the blood flow between the left ventricle and inlet side of the pump. The inlet pressure sensor may have any suitable form (Col. 2, lines 42-47 of Reich). Reich also discloses that a flat diaphragm is formed in a cannula through which the blood is channeled into the pump, and strain gauges are mounted on the diaphragm for measuring strain thereof which are indicative of pressure of the blood flow thereat (Col. 2, lines 47-53 of Reich). As discussed above, the structure of a pressure pump and its connecting pressure sensors and cannulas is well known in the art. And therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have used a structure and a tubular pressure sensor unit similar to the one taught by Bullister (as incorporated by reference by Reich) as part of the pressure measurement unit of Reich, in order to measure and monitor the pressure inside the

cannula linking the blood pump to the heart of the patient.

In reference to claim 23:

Reich teaches:

> An implantable blood pump (20 of Reich) which comprises an implantable cannula adapted to connect the heart of a patient to a blood pump (Col. 2, lines 24-29 and lines 54-65 of Reich). The pump includes means in the form of an inlet pressure sensor (22 of Reich) for measuring inlet pressure of the blood flow between the left ventricle and the inlet side of the pump (Col. 2, lines 42-45 of Reich). The pump also includes means in the form of an outlet pressure sensor (26 of Reich) joined to the outlet side of the pump in flow communication with the aorta by an outlet tube or catheter (28 of Reich).

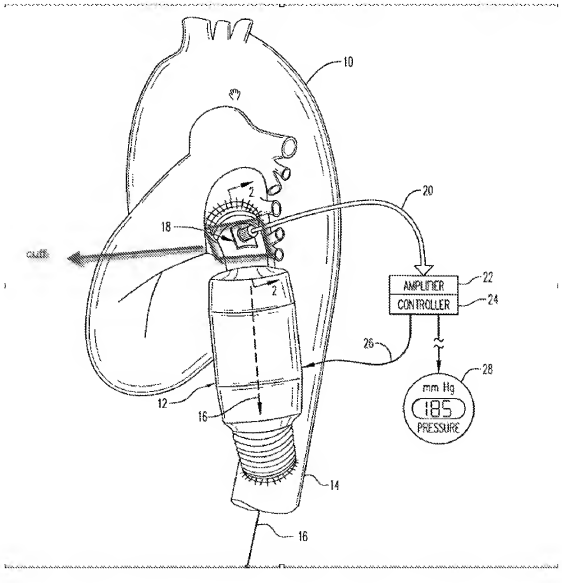
However Reich fails to disclose:

> A thin walled tubular member or a cuff with at least one pressure sensor within the cannula. The pressure sensor is positioned and adapted to non-invasively detect the pressure of blood flowing through the cannula from the heart to the pump.

Bullister, which has a common assignee as Reich, teaches:

> A tubular pressure sensor unit (18 of Bullister) joins a heart pump (12 of Bullister) in flow communication with the left ventricle for

carrying blood through the pump while simultaneously measuring pressure thereof (Col. 2, lines 44-53 of Bullister). The cannula further comprises a cuff within (the tubular section comprising element 18 of Bullister).



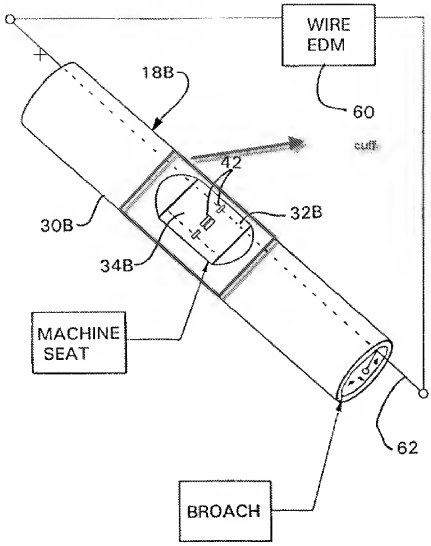


FIG. 10

The pressure sensor includes a cannula tube (30 of Bullister) through which the fluid is channeled. The tube is preferably formed from hemo-compatible material and is smooth and seamless. The tube comprises an annular thin wall with a nominal thickness (Col.

3, lines 1-6 of Bullister). A plurality of strain gauges (42 of Bullister) are mounted on top of the tube in order to measure the fluid pressure non-invasively (Fig. 2 of Bullister). The cannula comprises an interior wall (38 of Bullister).

Reich fails to disclose a specific structure for the cannulas connecting the pump pressure and the blood pressure sensors attached within each cannula. Reich also incorporates Bullister in order to describe the structural limitations of the pump which includes means in the form of an inlet pressure sensor (22 of Reich) for measuring inlet pressure of the blood flow between the left ventricle and inlet side of the pump. The inlet pressure sensor may have any suitable form (Col. 2, lines 42-47 of Reich). Reich also discloses that a flat diaphragm is formed in a cannula through which the blood is channeled into the pump, and strain gauges are mounted on the diaphragm for measuring strain thereof which is indicative of pressure of the blood flow thereat (Col. 2, lines 47-53 of Reich). As discussed above, the structure of a pressure pump and its connecting pressure sensors and cannulas is well known in the art. And therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have used a structure and a tubular pressure sensor unit similar to the one taught by Bullister (as incorporated by reference by Reich) as part of the pressure measurement unit of Reich, in order to measure and monitor the pressure inside the

cannula linking the blood pump to the heart of the patient.

In reference to claims 5, 8-9, 19 and 20:

Reich as modified by Bullister also teaches that the pressure sensor is connected to a controller (30 of Reich) in order to determine the pumping state of the heart from changes in the pressure (Col. 4, lines 15-31 of Reich). The pressure is used in a feed back mechanism which includes a controller to control a pumping speed of the pump (Col. 3, line 46-Col. 4, line 14 of Reich). The controller adjusts the pumping speed to minimize under-pumping and over-pumping by the pump (Col. 4, lines 33-40 and Col. 6, lines 145 of Reich).

In reference to claims 10 and 14:

The pressure sensor of Reich as modified by Bullister, comprises at least two spaced apart pressure sensors (A plurality of strain gauges 42 are mounted in the seat 32, Fig. 2 of Bullister).

In reference to claims 3 and 15:

The two spaced apart pressure sensors are aligned axially with respect to said implantable cannula (Fig. 2 of Bullister).

In reference to claim 24:

The substantially tubular body of the pressure sensing member is integrally formed within the body portion of the cannula (the sensor 18 is located on a recessed seat or pocket 32, Fig. 2 of Bullister).

In reference to claim 25:

The substantially tubular body of the pressure sensing member is positioned on the body portion of the cannula (Fig. 2 of Bullister).

In reference to claims 4 and 16:

Reich as modified by Bullister teaches all of the claim limitations; see the rejection of claims 1 and 13 above.

Bullister discloses that the sensors are aligned axially (Fig. 2 of Bullister). However, the combination fails to expressly teach that:

> The two spaced apart pressure sensors are aligned radially with respect to said implantable cannula.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to align the sensor radially. Applicant has not disclosed that aligning the pressure sensors radially provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected the

pressure sensors of Reich as modified by Bullister to perform equally well with either aligning arrangement.

Therefore, it would have been obvious to modify the alignment of the pressure sensors of Bullister to obtain the invention as specified in claims 4 and 16 because such modification would have been considered a mere design choice which fails to patentably distinguish over the prior art of Reich as modified by Bullister.

11. Claims 6, 18 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of Bullister as applied to claims 1 and 13 above, and further in view of US 3,240,207 to Barker et al (Hereinafter "Barker").

In reference to claims 6 and 18:

Reich as modified by Bullister teaches all of the claim limitations; see the rejection of claims 1 and 13 above.

Bullister also teaches that the cannula is preferably formed from hemo-compatible material (Col. 3, lines 1-6 of Bullister).

However, the combination fails to teach that:

> The thin walled tubular member or the cuff comprises silicone, velour, or polyethylene terephthalate.

Barker teaches:

> An implantable blood pressure monitor which comprises a cuff (flexible tube 10 of Barker) attached to a pressure sensor (13 of Barker) for measuring fluid pressure passing through a conduit (10 and 11 of Barker). The cuff and cannula are made of polyethylene terephthalate (Col. 2, lines 33-40 of Barker).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have used a hemo-compatible material for the cuff, such as the one taught by Barker, in the heart pump control of Reich as modified by Bullister in order to prevent the body from rejecting the implanted device.

In reference to claim 26:

Reich as modified by Bullister teaches all of the claim limitations; see the rejection of claim 23 above.

However the combination fails to teach that:

> The substantially tubular body of the pressure sensing member is positioned around the body portion of the cannula.

Barker teaches:

> An implantable blood pressure monitor which comprises a cuff (flexible tube 10 of Barker) attached to a pressure sensor (13 of Barker) for measuring fluid pressure passing through a conduit (10 and 11 of Barker). The cuff is wrapped around the cannula (Fig. 1

of Barker).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have used a blood pressure monitor similar to the one taught by Barker in place of the pressure measuring unit of Reich as modified by Bullister in order to measure blood pressure inside a cannula. Replacing one known element with another would have yielded predictable results.

12. Claims 7, 11 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of Bullister as applied to claims 1 and 13 above, and further in view of US 2003/0023255 to Miles et al (Hereinafter "Miles").

In reference to claims 7, 11 and 21-22:

Reich as modified by Bullister teaches all of the claim limitations; see the rejection of claims 1 and 13 above.

Reich also teaches that the blood pump is connected to the left ventricle via a catheter or tube by being sutured thereto (Col. 2, lines 54-57 of Reich).

However, the combination fails to teach that:

The implantable cannula includes a blood pump connector on one end thereof. The blood pump connector is screwably attachable to a blood pump.

Miles teaches:

> A cannula (10 of Miles) is used for connecting a blood pressure pump (52 of Miles) to the patient's heart (Fig. 1 of Miles). The cannula comprises a screw ring (28 of Miles) which will link the conduit (20 of Miles) to the pump and the cannula (26 of Miles) in a sealed manner (¶ [0057] of Miles).

It would have been obvious to one having ordinary skill in the art at time the applicant's invention was made to have used a screw ring similar to the one taught by Miles instead of the sutures and molding technique used in the pressure assist device of Reich as modified by Bullister in order to create a sealed connection between the pump and the cannula and from the cannula to the heart.

Double Patenting

13. Applicant is advised that should claims 7 and 11 be found allowable, claims 21 and 22 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anita Saidi whose telephone number is (571)270-3001. The examiner can normally be reached on Monday-Friday 9:30 am - 6:00 pm Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/A. S./
Examiner, Art Unit 3735
7/21/2008